CHANGES TO CLAIMS

The following listing of claims will replace all prior versions and listing of claims in the present application:

Listing of Claims:

1. (Original) A system for delivering at least one substance in at least two doses, comprising:

a drug container including a barrel, a first end extending from said barrel, and a stopper slidably positioned within said barrel;

a holder having a distal portion and a proximal portion, with the distal portion being assembled to the proximal portion, with the drug container secured therein; and

means for controlling the delivery of a substance contained in the barrel of the drug container including a plurality of slots extending axially along at least one of said portions of the holder whereby upon activation of said system, said portions of said holder move towards one another upon the application of a minimum force and said stopper moves a preselected axial distance to expel at least a portion of said substance from said drug container.

2. (Original) The system as described in claim 1, wherein said distal portion and said proximal portion of said holder are attached to one another by means of flexible members and corresponding openings to avoid premature activation of the system.

3. (Original) The system as described in claim 2, wherein said openings are formed by a portion of said distal portion bridging a space between a pair of flanges extending radially outwardly form said distal portion.

4. (Original) The system as described in claim 3, wherein said distal portion includes a skirt extending from the distal portion, including said bridging portion, and covering the means for controlling the delivery of the substance.

5. (Original) The system as described in claim 1, wherein said first end of said drug container includes a spray nozzle for use in intranasally delivering the substance and said drug container is a syringe.

6. (Original) The system as described in claim 5, further comprising a limiter associated with a first end of said distal portion, and said limiter limiting the depth of insertion of the spray nozzle into a nostril.

7. (Original) The system as described in claim 6, wherein said limiter is formed of a curved design to target specific areas in a nasal cavity.

8. (Original) The system as described in claim 5, wherein said spray nozzle is formed of a curved design to target specific areas in a nasal cavity.

9. (Original) The system as described in claim 1, further comprising a cap covering at least a first end of said distal portion.

10. (Original) The system as described in claim 9, wherein said cap includes an opening being formed by a portion of the cap extending across a space between the flanges.

11 (Original). The system as described in claim 9, wherein said cap includes a tamper evident means.

12. (Original) The system as described in claim 1, wherein said distal portion and said proximal portion of said holder each has a generally tubular interior configured to accommodate said drug container filled with a substance to be delivered and said proximal portion of said holder includes a closed end having a rod extending therefrom for engagement with said stopper of said drug container upon activation.

13. (Original) The system as described in claim 1, wherein said preselected axial distance corresponds to about a dosage of the substance held in said drug container barrel desired to be administered in a first motion of said stopper.

14. (Currently Amended) A system for delivering at least one substance in at least two doses, comprising:

a drug container including a barrel, a first end extending from said barrel, and a stopper slidably positioned within said barrel;

a holder having a distal portion and a proximal portion, with the distal portion being assembled to the proximal portion, with the drug container secured therein; and

means for controlling the delivery of a substance contained in the barrel of the drug container including a plurality of slots extending axially along at least one of said portions of the holder whereby upon activation of said system, said portions of said holder move towards one another upon the application of a minimum force and said stopper moves a preselected axial distance to expel at least a portion of said substance from said drug container;

wherein said preselected axial distance corresponds to about a dosage of the substance held in said drug container barrel desired to be administered in a first motion of said stopper;

~~The system as described in claim 13,~~ wherein said preselected axial distance corresponds to about half the distance that said stopper is capable of moving within said barrel to administer about half of the substance held by said drug container.

15. (Original) The system as described in claim 1, said system further comprising a means for securing said drug container in said distal portion of said holder with said distal portion having a first end through which the first end of said drug container can extend and a second, open end defining an opening of sufficient size for receiving the drug container.

16. (Original) The system as described in claim 15, wherein said drug container is a syringe having a rim extending from an open end thereof and said drug container securing means

is situated adjacent said open end of said distal portion and includes at least one detent situated adjacent the open end and dimensioned so that the rim of the syringe may be securely retained in said distal portion by said detent.

17. (Original) The system as described in claim 1, further comprising a pair of flanges extending radially outwardly from said distal portion of said holder and attached thereto by a plurality of ribs.

18. (Original) The system as described in claim 1, wherein said distal portion includes at least one pair of ribs and wherein said slots in said proximal portion of said holder include at least one pair of slots situated thereof, with said pair of slots including a first slot and a second slot extending axially along the body of the proximal portion of the holder generally parallel to each other and dimensioned and situated to accommodate the ribs so that one of said ribs is insertable into each slot and able to travel along the slot upon activation of the system.

19. (Original) The system as described in claim 18, wherein the first slot is preferably open and is divided into at least two portions, and situated adjacent an open end of the first slot is a bridge extending across at least a portion of the slot, with the bridge being dimensioned so that when a rib comes in contact with the bridge and sufficient force is applied there against, the bridge will fracture to allow passage of the rib along the slot.

20. (Original) The system as described in claim 19, wherein a detent is situated adjacent the open end of the first portion of the first slot so that the rib can be clipped between the detent and the bridge prior to activation of the system, and the second portion of the first slot is at least slightly offset from the first portion of the first slot and towards the second slot.

21. (Original) The system as described in claim 20, wherein the other rib travels along the second slot to provide structural stability and tracking, with the second slot including biasing means for biasing the rib in the first slot towards the second portion of the slot upon release of the force applied by a user.

22. (Currently Amended) A system for delivering at least one substance in at least two doses, comprising:

a drug container including a barrel, a first end extending from said barrel, and a stopper slidably positioned within said barrel;

a holder having a distal portion and a proximal portion, with the distal portion being assembled to the proximal portion, with the drug container secured therein; and

means for controlling the delivery of a substance contained in the barrel of the drug container including a plurality of slots extending axially along at least one of said portions of the holder whereby upon activation of said system, said portions of said holder move towards one another upon the application of a minimum force and said stopper moves a preselected axial distance to expel at least a portion of said substance from said drug container;

wherein said distal portion includes at least one pair of ribs and wherein said slots in said proximal portion of said holder include at least one pair of slots situated thereof, with said pair of slots including a first slot and a second slot extending axially along the body of the proximal portion of the holder generally parallel to each other and dimensioned and situated to accommodate the ribs so that one of said ribs is insertable into each slot and able to travel along the slot upon activation of the system;

wherein the first slot is preferably open and is divided into at least two portions, and situated adjacent an open end of the first slot is a bridge extending across at least a portion of the slot, with the bridge being dimensioned so that when a rib comes in contact with the bridge and sufficient force is applied there against, the bridge will fracture to allow passage of the rib along the slot;

wherein a detent is situated adjacent the open end of the first portion of the first slot so that the rib can be clipped between the detent and the bridge prior to activation of the system, and the second portion of the first slot is at least slightly offset from the first portion of the first slot and towards the second slot.;

wherein the other rib travels along the second slot to provide structural stability and tracking, with the second slot including biasing means for biasing the rib in the first slot towards the second portion of the slot upon release of the force applied by a user;

~~The system as described in claim 21,~~ wherein said biasing means is adapted to include a cut-away portion forming a deflectable arm having an inner wall associated with the second slot so that as the ribs travel along their respective slots, the one rib will deflect the flexible arm to cause the proximal portion of the holder to rotate relative to the distal portion about a central axis

so that the rib situated in the first slot can come in contact with a second bridge so that upon sufficient force being applied, the bridge will fracture to allow passage of the rib along the second portion of the first slot.

23. (Original) The system as described in claim 1, wherein said distal portion of said holder includes at least one window to permit visual inspect of the contents of the drug container located within the holder.

24. (Original) A holder for a drug container, comprising;

a distal portion and a proximal portion, each having configured to accommodate a drug container filled with a substance to be delivered, with the distal portion being able to be assembled to the proximal portion; and

means for controlling the delivery of the substance including a plurality of slots extending axially along at least one of said portions of the holder whereby when said portions of said holder are moved towards one another upon the application of a minimum force, at least a portion of the substance can be expelled from said drug container.

25. (Original) The holder as described in claim 24, wherein a first end of said drug container includes a spray nozzle and said drug container is a syringe, and said distal portion and said proximal portion each has a generally tubular interior configured to accommodate said syringe and said proximal portion of said holder includes a closed end having a rod extending therefrom for engagement with said stopper of said syringe during activation.

26. (Original) The holder as described in claim 24, wherein said preselected axial distance corresponds to about a dosage of the substance held in said drug container desired to be administered.

27. (Original) The holder as described in claim 26, wherein said distal portion further comprises a means for securing said drug container therein with said distal portion having a first end through which a first end of said drug container can extend and a second, open end defining an opening of sufficient size for receiving a barrel of the drug container.

28. (Original) The holder as described in claim 27, further comprising a pair of flanges extending radially outwardly from said distal portion and attached there along by a plurality of ribs.

29. (Original) The holder as described in claim 28, wherein said slots in said proximal portion of said holder include at least one pair of slots situated thereon, with said pair of slots including a first slot and a second slot extending axially along the body of the proximal portion of the holder generally parallel to each other and dimensioned and situated to accommodate the ribs so that the ribs are insertable into the slots and able to travel along the slots upon activation of the system.

30. (Original) The holder as described in claim 29, wherein the first slot is preferably open and is divided into at least two portions, and situated adjacent an open end of the first slot is a bridge extending across at least a portion of the slot, with the bridge being dimensioned so that when a rib comes in contact with the bridge and sufficient force is applied there against, the bridge will fracture to allow passage of the rib along the slot.

31. (Original) The holder as described in claim 30, wherein a detent is situated adjacent said open end of the first portion of the first slot so that the rib can be clipped between the detent and the bridge prior to activation of the system, and the second portion of the first slot is at least slightly offset from the first portion of the first slot and towards the second slot.

32. (Original) The holder as described in claim 31, wherein one of said ribs travels along the second slot to provide structural stability and tracking, with the second slot including biasing means for biasing the rib in the first slot towards the second portion of the slot upon release of the force applied by a user.

33. (Original) The holder as described in claim 24, wherein said distal portion includes at least one window to permit visual inspect of the contents of the drug container when located within the holder.

34. (Original) The holder as described in claim 24, wherein said distal portion and said proximal portion of said holder are attached to one another by means of flexible members and corresponding openings to avoid premature activation.

35. (Original) The holder as described in claim 34, wherein said openings are formed by a portion of said distal portion bridging a space between a pair of flanges extending radially outwardly form said distal portion.

36. (Original) The holder as described in claim 35, wherein said distal portion includes a skirt extending from the distal portion, including said bridging portion, and covering the means for controlling the delivery of the substance.

37. (Original) The holder as described in claim 24, wherein said first end of said drug container includes a spray nozzle for use in intranasally delivering the substance and said drug container is a syringe.

38. (Original) The holder as described in claim 37, further comprising a limiter associated with a first end of said distal portion, and said limiter limiting the depth of insertion of the spray nozzle into a nostril.

39. (Original) The holder as described in claim 38, wherein said limiter is formed of a curved design to target specific areas in a nasal cavity.

40. (Original) The holder as described in claim 37, wherein said spray nozzle is formed of a curved design to target specific areas in a nasal cavity.

41. (Original) The holder as described in claim 24, further comprising a cap covering at least a first end of said distal portion.

42. (Original) The holder as described in claim 41, wherein said cap includes an opening being formed by a portion of the cap extending across a space between the flanges.

43. (Original) The holder as described in claim 41, wherein said cap includes a tamper evident means.

44. (Original) A system for the nasal delivery of at least one substance, comprising:

a syringe including a barrel, a first end extending from said barrel, said first end including a spray nozzle having an opening for dispensing the substance from said barrel, and at least one stopper slidably positioned within said barrel;

a holder having a distal portion and a proximal portion, each having a generally tubular interior configuration to accommodate said syringe, with the distal portion being able to be assembled to the proximal portion, which acts as a plunger rod during activation of the system; and

means for controlling the delivery of a substance including a plurality of slots extending axially along at least one of said portions of the holder whereby upon activation of said system, said portions of said holder move towards one another upon the application of a minimum force and said stopper moves a preselected axial distance to expel at least a portion of said substance from said syringe, with said preselected axial distance corresponding to about half the distance that said stopper is capable of moving within said barrel to administer about half of the substance contained by said syringe barrel.

45. (Original) The system as described in claim 44, further comprising a pair of flanges extending radially outwardly from said distal portion of said holder and attached there along by a plurality of ribs.

46. (Original) The system as described in claim 45, wherein said slots in said proximal portion of said holder include two corresponding sets situated on each side thereof, with each set including a first slot and a second slot extending axially along the body of the proximal portion of the holder generally parallel to each other and dimensioned and situated to accommodate the ribs so that the ribs are insertable into the slots and able to travel along the slots upon activation of the system.

47. (Original) The system as described in claim 46, wherein the first slot is preferably open and is divided into at least two portions, and situated adjacent an open end of the first slot is a bridge extending across at least a portion of the slot, with the bridge being dimensioned so that

when a rib comes in contact with the bridge and sufficient force is applied there against, the bridge will fracture to allow passage of the rib along the slot.

48. (Original) The system as described in claim 47, wherein a detent is situated adjacent said open end of the first portion of the first slot so that the rib can be clipped between the detent and the bridge prior to activation of the system and the second portion of the first slot is at least slightly offset from the first portion of the first slot and towards the second slot.

49. (Original) The system as described in claim 48, wherein one of said ribs travels along each of said second slots to provide structural stability and tracking, with each second slot including a cut-away portion forming a deflectable arm for biasing the ribs in the first slots towards the second portions of the slots upon release of the force applied by a user so that as the ribs travel along their respective slots, the ribs traveling along the second slots will deflect the flexible arms to cause the proximal portion of the holder to rotate relative to the distal portion about a central axis so that the ribs situated in the first slots each come in contact with a second bridge so that upon sufficient force being applied, the bridges will each fracture to allow passage of the ribs along the second portions of the first slots.

50. (Original) The system as described in claim 44, wherein said distal portion of said holder includes at least one window to permit visual inspect of the contents of the syringe located within the holder.

51. (Original) The system as described in claim 44, wherein said distal portion and said proximal portion of said holder are attached to one another by means of flexible members and corresponding openings to avoid premature activation of the system.

52. (Original) The system as described in claim 51, wherein said openings are formed by a portion of said distal portion bridging a space between a pair of flanges extending radially outwardly form said distal portion.

53. (Original) The system as described in claim 52, wherein said distal portion includes a skirt extending from the distal portion, including said bridging portion, and covering the means for controlling the delivery of the substance.

54. (Original) The system as described in claim 44, wherein said first end of said drug container includes a spray nozzle for use in intranasally delivering the substance and said drug container is a syringe.

55. (Original) The system as described in claim 54, further comprising a limiter associated with a first end of said distal portion, and said limiter limiting the depth of insertion of the spray nozzle into a nostril.

56. (Original) The system as described in claim 55, wherein said limiter is formed of a curved design to target specific areas in a nasal cavity.

57. (Original) The system as described in claim 55, wherein said spray nozzle is formed of a curved design to target specific areas in a nasal cavity.

58. (Original) The system as described in claim 44, further comprising a cap covering at least a first end of said distal portion.

59. (Original) The system as described in claim 58, wherein said cap includes an opening being formed by a portion of the cap extending across a space between the flanges.

60. (Original) The system as described in claim 58, wherein said cap includes a tamper evident means.

61. (Original) A method of intranasally delivering at least one substance in at least two doses, comprising the steps of:

grasping a pre-assembled drug delivery system with a thumb and two forefingers of one hand, said drug delivery system including a drug container and a holder, with the drug container including a barrel, a first end extending from the barrel, and a stopper slidably positioned within the barrel and the holder having a distal portion and a proximal portion, with the distal portion being assembled to the proximal portion, with the drug container secured therein, and the proximal portion acting as a plunger rod during activation of the system;

inserting the end of said drug container into one nostril of a person to whom the substance is to be intranasally delivered;

squeezing together the thumb and two forefingers of the one hand to apply sufficient force to overcome a bridge extending at least partially across a slot to insure the application of a minimum force;

moving the proximal portion of the holder towards the distal portion of the holder a first predetermined distance during a first motion as a result of continuing to squeeze together the thumb and two forefingers to cause the displacement of the stopper and expulsion of a first predetermined amount of a substance contained in the chamber of the drug container barrel into said nostril;

removing the end of said drug container from said nostril while relaxing the squeezing force being applied and inserting the end of said drug container into another nostril of the person to whom the substance is to be intranasally delivered;

squeezing together the thumb and two forefingers to apply sufficient force to overcome a second bridge extending at least partially across the slot to insure the application of a minimum force; and

moving the proximal portion of the holder towards the distal portion of the holder a second predetermined distance during a second motion as a result of continuing to squeeze together the thumb and two forefingers to cause the displacement of the stopper and expulsion of a second predetermined amount of the substance contained in the chamber of the drug container barrel into said other nostril.

62. (Original) The method described in claim 61 wherein said first predetermined distance is approximately equal to said second predetermined distance and said first predetermined amount of substance expelled is approximately equal to said second predetermined amount of substance expelled.

63. (Original) The method described in claim 61, further comprising the step of visually inspecting the contents of the drug container located within the holder through at least one window located in said distal portion of said holder.

64. (Original) The method described in claim 61, wherein relaxing the force being applied during said first motion causes the proximal portion of the holder to rotate about its axis by a force exerted by biasing means.

65. (Original) The method described in claim 61, wherein the step of grasping the drug delivery device includes placing each of the two forefingers on a flange extending from the distal portion of the holder and placing the thumb on a closed end of the proximal portion of the holder.

66. (Original) The method described in claim 61, further comprising the step of removing a tip cap from the end of the drug container before inserting the end of said drug container into the one nostril of the person to whom the substance is to be intranasally delivered.

67. (Currently Amended) A method of intranasally delivering at least one substance in at least two doses, comprising the steps of:

grasping a pre-assembled drug delivery system with a thumb and two forefingers of one hand, said drug delivery system including a drug container and a holder, with the drug container including a barrel, a first end extending from the barrel, and a stopper slidably positioned within the barrel and the holder having a distal portion and a proximal portion, with the distal portion being assembled to the proximal portion, with the drug container secured therein, and the proximal portion acting as a plunger rod during activation of the system;

inserting the end of said drug container into one nostril of a person to whom the substance is to be intranasally delivered;

squeezing together the thumb and two forefingers of the one hand to apply sufficient force to overcome a bridge extending at least partially across a slot to insure the application of a minimum force;

moving the proximal portion of the holder towards the distal portion of the holder a first predetermined distance during a first motion as a result of continuing to squeeze together the thumb and two forefingers to cause the displacement of the stopper and expulsion of a first predetermined amount of a substance contained in the chamber of the drug container barrel into said nostril;

removing the end of said drug container from said nostril while relaxing the squeezing force being applied and inserting the end of said drug container into another nostril of the person to whom the substance is to be intranasally delivered;

squeezing together the thumb and two forefingers to apply sufficient force to overcome a second bridge extending at least partially across the slot to insure the application of a minimum force; and

moving the proximal portion of the holder towards the distal portion of the holder a second predetermined distance during a second motion as a result of continuing to squeeze together the thumb and two forefingers to cause the displacement of the stopper and expulsion of a second predetermined amount of the substance contained in the chamber of the drug container barrel into said other nostril;

~~The method described in claim 61,~~ wherein inserting the end of said drug container includes inserting a spray nozzle on the first end of said drug container for use in intranasally delivering the substance.

68. (Original) The method described in claim 67, wherein inserting the end of said drug container includes inserting a limiter associated with a first end of said distal portion, and said limiter limiting the depth of insertion of the spray nozzle into a nostril.

69. (Original) The method described in claim 68, wherein inserting said limiter includes inserting a limiter formed of a curved design to target specific areas in a nasal cavity.

70. (Original) The method described in claim 67 wherein inserting said spray nozzle includes inserting a spray nozzle formed of a curved design to target specific areas in a nasal cavity.

71. (Original) The method described in claim 61, further comprising the step of removing a cap covering at least a first end of said distal portion before grasping the pre-assembled drug delivery system.

72. (Original) The method described in claim 71, wherein removing said cap includes breaking a tamper evident means.

73. (Original) The method described in claim 61 wherein said substance is a drug selected from the group consisting of Anti-Angiogenesis agents, Antisense, anti-ulcer, butorphanol, Calcitonin and analogs, COX-II inhibitors, desmopressin and analogs, dihydroergotamine, Dopamine agonists and antagonists, Enkephalins and other opioid peptides, Growth hormone and analogs (including growth hormone releasing hormone), Growth hormone antagonists, IgE suppressors, Insulin, insulinotropin and analogs, Ketamine, Kytril, Leutenizing hormone releasing hormone and analogs, lidocaine, metoclopramide, Midazolam, Narcotic analgesics, neuraminidase inhibitors, nicotine, Non-steroid anti-inflammatory agents, Oligosaccharides, ondansetron, Parathyroid hormone and analogs, Parathyroid hormone antagonists, Prostaglandin antagonists, Prostaglandins, Recombinant soluble receptors, scopolamine, Serotonin agonists and antagonists, Sildenafil, Terbutaline, vasopressin.

74. (Original) The method described in claim 61 wherein said substance is a vaccine vaccines with or without carriers/adjuvants selected from the group consisting of prophylactics

and therapeutic antigens (including but not limited to subunit protein, peptide and polysaccharide, polysaccharide conjugates, toxoids, genetic based vaccines, live attenuated, reassortant, inactivated, whole cells, viral and bacterial vectors) in connection with, arthritis, cholera, cocaine addiction, HIB, meningococcus, measles, mumps, rubella, varicella, yellow fever, Respiratory syncytial virus, pneumococcus, streptococcus, typhoid, influenza, hepatitis, including hepatitis A, B, C and E, polio, HIV, parainfluenza, rotavirus, CMV, chlamydia, non-typeable haemophilus, moraxella catarrhalis, human papilloma virus, tuberculosis including BCG, gonorrhoea, asthma, atheroschlerosis, malaria, otitis media, E-coli, Alzheimers, H. Pylori, salmonella, diabetes, cancer and herpes simplex.

75. (Original) The method described in claim 61 wherein said substance is a therapeutic substance selected from the group consisting of Agents for the common cold, Anti-addiction, anti-infectives, analgesics, anesthetics, anorexics, antiarthritics, anti-allergy agents, antiasthmatic agents, anticonvulsants, anti-depressants, antidiabetic agents, anti-depressants, anti-diuretics, anti-emetics, antihistamines, anti-inflammatory agents, antimigraine preparations, antimotion sickness preparations, antinauseants, antineoplastics, anti-obesity, antiosteoporeteic, antiparkinsonism drugs, antipruritics, antipsychotics, antipyretics, anticholinergics, benzodiazepine antagonists, bone stimulating agents, central nervous system stimulants, hormones, hypnotics, immunosuppressives, prostaglandins, proteins, peptides, polypeptides and other macromolecules, psychostimulants, rhinitis treatment, sedatives, sexual hypofunction, tranquilizers and vitamins including B12.

76. (Currently Amended) The method described in claim ~~1~~ 61 wherein said substance is an influenza vaccine.

77. (New) The method described in claim 61 wherein said substance is a vaccine.

78. (New) A method of intranasally delivering a substance in two doses, said method comprising the steps of:

grasping a pre-assembled drug delivery system with one hand, said drug delivery system including a drug container and a holder having a distal part and a proximal part and with the drug container being held by the distal part, the drug container including a barrel having an end and a stopper slidably positioned within the barrel;

inserting the end of said drug container barrel into a first nostril of a person to whom the substance is to be intranasally delivered;

squeezing together the distal and proximal parts of said holder so as to apply a force and move the proximal part of said holder towards the distal part of said holder a first predetermined distance during a first motion causing displacement of the stopper and expulsion of a first predetermined amount of the substance into the first nostril of the person to whom the substance is to be intranasally delivered;

removing the end of said drug container from the first nostril;

inserting the end of said drug container into a second nostril of the person to whom the substance is to be intranasally delivered;

squeezing together the distal and proximal parts of said holder so as to apply a force and move the proximal part of said holder towards the distal part of said holder a second predetermined distance during a second motion causing displacement of the stopper and expulsion of a second predetermined amount of the substance into the second nostril of the person to whom the substance is to be intranasally delivered.

79. (New) The method described in claim 78, wherein said substance is an influenza vaccine.

80. (New) The method described in claim 78, wherein said substance is a vaccine.